

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ding *et al.*

Application No.: to be assigned

Group Art Unit: to be assigned

Filed: February 7, 2002

Examiner: to be assigned

For: MEDICAL DEVICE WITH SPONGE
COATING FOR CONTROLLED
DRUG RELEASE

Attorney Docket No.: 10177-111-999
Divisional of application serial no:
09/060,071, filed April 14, 1998

PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants respectfully request that the following amendment and remarks be made of record in the above-identified application. Annexed hereto as Exhibit A which is a set of marked-up claims and Exhibit B which is a set of pending claims after entry of the amendment.

IN THE CLAIMS

Please cancel claims 1-13, and 34-46 without prejudice. Applicants reserve the right to prosecute the canceled subject matters in one or more related applications.

Please amend claim 16 to recite as follows:

16. (Amended) The catheter of claim 14 wherein the void space of the sponge coating is greater than about 60% of the volume of the sponge coating.

REMARKS

Claims 14-33 appear in the present application for the Examiner's consideration. Claim 16 has been amended to more particularly point out and distinctly claim the present invention. Specifically claim 16 has been amended to recite that the void space of the sponge coating is greater than about 60% of the volume of the sponge coating. Support

for this amendment is found in the specification at page 3, lines 12-13. No new matter has been added.

CONCLUSION

Applicants respectfully request that the amendment and remarks of the preliminary amendment be entered and made of record in the instant application. Favorable consideration of Applicants claimed invention is respectfully solicited.

No fee is believed due. However, if the Examiner determines that any fee is due, please charge the required fee to Pennie & Edmonds LLP Account No. 16-1150.

Respectfully submitted,

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Marked-up Copy of Claim 16

16. (Amended) The catheter of claim 14 wherein the [voids are] void space of the
sponge coating is greater than about 60% of the volume of the sponge coating.

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Exhibit B-Pending Claims

14. A catheter for delivering a biologically active material to a desired location of a body lumen of a patient comprising an expandable portion which is insertable or implantable into a body lumen, wherein the expandable portion is expandable in response to inflation pressure to fill the cross-section of the lumen and engage the tissue of the lumen and wherein the expandable portion comprises:

- a) a reservoir defined by a membrane having a plurality of pores therein, and wherein the reservoir is capable of containing the biologically active material and is connected to a reservoir lumen for filling the reservoir with the biologically active material;
- b) a sponge coating for release of at least one biologically active material disposed about the membrane, wherein the sponge coating comprises a non-hydrogel polymer having a plurality of voids; and
- c) means for infusing the biologically active material into the voids.

15. The catheter of claim 14 wherein the voids are formed by eluting a particulate material from the polymer.

16. The catheter of claim 14, wherein the void space of the sponge coating is greater than about 60% of the volume of the sponge coating.

17. The catheter of claim 14 wherein the infusion means comprises an inflation lumen connected to a balloon disposed wherein the reservoir.

18. The catheter of claim 14 wherein the expandable portion further comprises a perfusion lumen for sustained infusion of the biologically active material into the voids and inflation of the expandable portion.

19. The catheter of claim 14 which further comprises control means for synchronizing the deflation of the expandable portion and the infusion of the biologically active material into the voids.

20. The catheter of claim 14 wherein the polymer comprises an elastomer.

21. The catheter of claim 20 wherein the elastomer is selected from the group consisting of silicones, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, polyisobutylene and its copolymers, and EPDM rubbers.

22. The catheter of claim 14 wherein the biologically active material is heparin.

23. A method of making a medical device having at least an expandable portion for insertion or implantation into the body of a patient, wherein the portion has a surface which is adapted for exposure to body tissue of the patient and wherein at least a part of the surface is covered with a coating to release at least one biologically active material therefrom, the method comprising:

- a) forming a sponge coating by
 - i) applying a composition comprising a non-hydrogel polymer and a particulate material to the surface and
 - ii) exposing the surface to a fluid to elute the particulate material from the polymer, and
- b) loading the sponge coating with the biologically active material.

24. The method of claim 23 wherein the fluid is a solvent.

25. The method of claim 23 wherein the fluid is a body fluid.

26. The method of claim 23 wherein the particulate material is eluted *in vivo* while the device is inserted or implanted in the body to form a plurality of voids in the sponge coating and wherein the voids are greater than about 60% of the volume of the sponge coating.

27. The method of claim 24 wherein the particulate material is a biologically active material.

28. The method of claim 23 wherein the biologically active material is loaded into the sponge coating by dipping the surface into a composition comprising the biologically active material.

29. The method of claim 23 wherein the polymer comprises an elastomer.

30. The method of claim 29 wherein the elastomer is selected from the group consisting of silicones, polyurethanes, thermoplastic elastomers, ethylene vinyl acetate copolymers, polyolefin elastomers, polyisobutylene and its copolymers, and EPDM rubbers.

31. The method of claim 23 wherein the biologically active material is heparin.

32. The method of claim 23 wherein the particulate material is selected from the group consisting of polyethylene oxide, polyethylene glycol, polyethylene oxide/polypropylene oxide copolymers, polyhydroxyethyl methacrylate, polyvinylpyrrolidone, polyacrylamide and its copolymers, salts, sugars, and elutable biologically active materials.

33. The method of claim 23 further comprising curing the composition prior to exposing the surface to a solvent to elute the particulate material from the polymer.